

Initial Experience With an Autocapture Pacemaker System

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Abstract

Introduction: Autocapture management aims to extend pacemaker longevity without compromising on patient safety by automatically monitoring the pacing threshold and adjusting the pacemaker output for consistent capture. This paper describes our initial experience with the Pacesetter Regency pacemaker with autocapture management. **Materials and Methods:** Nineteen patients were implanted with single chamber pacemakers with autocapture management. Autocapture was programmed "ON" the day after implantation if Evoked Response (ER) amplitude was at least 2.8 mV. The patients were followed up at 2 weeks, 2 months and 6 months. At each visit, pacing threshold and lead impedance were measured. Autocapture was turned "ON" during follow-up if it had not been done previously. **Results:** In 16 out of 19 patients, autocapture could be turned "ON" the day after implantation. One patient had an ER signal that was less than 2.8 mV and 2 patients were in fast atrial fibrillation of more than 120 beats per minute which precluded ER signal testing. These patients could not have autocapture programmed "ON". **Conclusion:** The benefits of autocapture management can only be realised if an ER signal of at least 2.8 mV is obtained. This requires intraoperative testing of the ER signal. Since there is no commercially available pacing system analyser presently that can measure this, modification of the standard implantation procedure with some prolongation of procedure time is needed.

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Introduction

The longevity of a pacemaker generator varies directly with the total deliverable amount of electrical charge (Q, in coulombs) and inversely with the rate of consumption of charge. The rate of consumption is dependent in turn on the total number of electrical pulses per unit time, and the strength of each pulse, measured in terms of pulse amplitude (V, in volts) and pulse duration in milliseconds. Q is a fixed quantity for any particular pacemaker battery. By varying the rate of pacing and the strength of each stimulus, considerable savings can be made in energy consumption, thus extending the life of the battery. However, the patient's physiological needs and function determine the rate of pacing and the percentage of time the patient is dependent on the pacemaker. For example, a patient who is extremely bradycardic or who has no intrinsic heart rhythm will be totally pacemaker dependent. Another patient with poor ventricular function and a fixed stroke volume may be highly dependent on a higher heart rate to maintain adequate cardiac output. Conventionally, the pulse amplitude is programmed to twice the threshold value, or the pulse duration is programmed to thrice the threshold value. This conserves energy without compromising patient safety.

However, this strategy is limited in situations where the chronic pacing threshold is high. A new approach to this problem is autocapture management. Beat-to-beat changes in pacing threshold are measured and the pulse amplitude is altered automatically to 0.3 V above the threshold value in a dynamic fashion. Such an approach has been estimated to extend pacemaker longevity by up to three times or 22 years for a rate-responsive single chamber pacing system. This article describes our institutional experience with the first 19 patients using the autocapture management system.

Materials and Methods

A total of 19 patients were implanted with single chamber pacemakers [VVI (ventricular) or VVIR (ventricular rate-responsive)] possessing the autocapture management system. We used the pacemaker models Regency™ SC+ or Regency™ SR+ from Pacesetter AB in conjunction with a low polarisation, low threshold bipolar Membrane™ lead model 140X, or Membrane E™ lead model 145X. The use of a low polarisation lead is essential to enable detection of myocardial capture by the Evoked Response (ER) signal. During implantation, R wave amplitude and pacing threshold were measured using a pacing system analyser.

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For successful implantation, an R wave amplitude greater than or equal to 5 mV and pacing threshold less than or equal to 1.0 V at a pulse width of 0.5 ms were accepted. One day following implant, the lead polarisation signal and ER signal were measured using the APS™ II programmer and autocapture was programmed “ON” only if an ER signal of at least 2.8 mV could be obtained. For autocapture management, sensing polarity was programmed to bipolar and pacing polarity to unipolar. Follow-up visits were scheduled at 2 weeks, 2 months, and 6 months and subsequently at half-yearly or yearly intervals at the discretion of the attending pacemaker physician. At each follow-up visit, the ER and PR signals, pacing threshold and pacing lead impedance were measured, and ER and PR sensitivities were programmed appropriately to achieve at least a 2-fold safety margin. Only if the ER signal was less than 2.8 mV was autocapture programmed “OFF”.

Results

The mean age of the patients was 68 ± 11 years (range 48 to 87 years). There were 8 VVI and 11 VVIR systems. The mean pacing threshold at implant was 0.42 ± 0.26 V. The mean pacing lead impedance at implant was $745 \pm 177 \Omega$. At the 2-week follow-up, mean pacing threshold and impedance were 0.77 ± 0.54 V and $775 \pm 182 \Omega$, respectively. At the 2-month follow-up, mean pacing threshold and impedance were 0.80 ± 0.51 V and $661 \pm 99 \Omega$, respectively. At the 6-month follow-up, the mean pacing threshold and impedance were 0.69 ± 0.47 V and $736 \pm 191 \Omega$, respectively. Autocapture could be programmed “ON” for all except 3 patients. In 1 patient, the ER signal was less than 2.8 mV and hence autocapture could not be turned on. Two patients had fast atrial fibrillation and a ventricular response of greater than 120 beats per minute. In those 2 patients, the ER signal could not be tested since the ER sensitivity test is conducted automatically at a rate of 100 beats per minute and can only be increased to a maximum rate of 120 beats per minute.

Discussion

The concept of an automatic threshold-tracking pacemaker is not new. It was first discussed in the 1970s by Preston and Bowers.¹ Such a system must incorporate automatic capture verification and automatic adjustment of pacing output to maintain an adequate safety margin. In addition, it must also guarantee patient safety by automatic generation of a high output safety pulse to ensure capture once non-capture is detected (see Figure 1 for an explanation of how an autocapture threshold test is done). Such a system has now been realised in the Pacesetter family of autocapture pacemakers, namely in models such as Microny, Regency and Affinity.

Our experience with the first 19 patients with the

Pacesetter Regency pacemakers shows that pacing threshold rises significantly from implant values for up to 2 months after implant. At 6-month follow-up, thresholds decrease to values that are not significantly different from implant. Lead impedance shows an initial rise at 2 weeks and then returns to values that are close to implant from 2 months onwards. The autocapture function could only be programmed “ON” if the following conditions were met: 1) the polarisation signal was less than 60% of the suggested ER sensitivity setting and 2) the sensed ER signal was at least 2.8 mV. The ER signal cannot be measured using the ordinary pacing system analyser. During the implantation procedure, the lead has to be connected to the pulse generator and the Pacesetter APS II programmer, with a telemetry wand wrapped in a sterile sleeve, has to be placed over the pacemaker in order to measure the ER signal. We felt that this would prolong the procedure unnecessarily and therefore chose to implant the system in the usual way, using only measured sensed R wave and pacing threshold from the pacing system analyser to determine a suitable site for the pacing electrode. The ER signal was measured on the day following implant using the programmer, and autocapture was programmed “ON” only if the above criteria were met. Using this approach, we found that 1 patient could not have the autocapture function programmed “ON” because of an inadequate ER signal, although the pacing threshold and intrinsic R wave amplitude (PR signal) were satisfactory. Two patients with fast atrial fibrillation could not have the Autocapture function programmed “ON” because the ER signal could not be tested. Therefore, 3 out of 19 or 16% failed to utilise the autocapture function.

In the original clinical study of Clarke et al,² 10% of patients had to have the lead position readjusted at least once in order to satisfy implant criteria for ER signal as well as standard sensing and pacing threshold criteria. However, the ER criteria in that study were more stringent (>4.5 mV). In that study, it was also found that there was poor correlation between the ER signal and the R wave amplitude. While the concept of autocapture management is extremely attractive, its successful implementation hinges on adequate ER signals for confirmation of capture. A minimum ER signal of 2.8 mV is a prerequisite for autocapture since the maximum ER sensitivity available is 1 mV. Current manufacturer recommendations for ER signal testing, which involves connecting the lead to the pulse generator and using the programmer with the telemetry wand in a sterile sleeve before deciding on the final lead position, must be followed in order to ensure a successful outcome. This may be regarded as cumbersome to some operators and certainly will add to the procedure time. New pacing system analysers which can measure the ER signal would circumvent this problem. Fast atrial fibrillation greater than 120 beats per

Fig. 1. Example of an autocapture threshold test in a patient with an implanted autocapture pacemaker. The output is lowered in 0.3 V decrements until there is loss of capture. In the sixth beat of the top panel, a stimulus of 0.3 V fails to capture the heart. A backup pulse of 4.5 V follows 62.5 ms later and captures the heart, preventing ventricular standstill. The seventh beat at 0.3 V again confirms loss of capture and the backup pulse of 4.5 V again captures the heart. The bottom panel shows capture of the heart at a stimulus strength of 0.6 V for two beats, confirming that the threshold is 0.6 V. The output is then set at 0.9 V (0.3 V above the threshold). If the threshold changes at any time, the threshold search sequence is again repeated, ensuring that there is always consistent capture of the heart without an excessively high output, therefore conserving energy.

minute during the implantation procedure is also another problem with the current algorithm for ER signal testing and would require the use of short acting beta-blockers to slow the heart rate before the test can be performed.

Conclusion

Our initial experience with the Pacesetter Autocapture pacemaker system is encouraging. However, to ensure that the autocapture system will work, it is paramount to ensure that an adequate ER signal is established at the time of implantation. However, further improvements can be made to facilitate the ease of implantation by clinicians. A new pacing system analyser capable of measuring ER signals in addition to conventional pacing and sensing thresholds would certainly reduce procedure time. More research is

also needed to assess the stability of ER signals over time, since this would impact greatly on the successful and safe operation of the Autocapture system.

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